

## **REMARKS**

### **I. Examiner Interview**

Applicant thanks the Examiner and Supervisory Examiner for the courtesies extended during the telephone interview of December 7, 2010. Further to the RCE and Amendment under 37 C.F.R. § 1.114 filed on November 19, 2010, and in accordance with the recommendation of the Examiner and Supervisor, Applicant submits a Supplemental Amendment which includes remarks regarding the interview discussion.

### **II. Status of Claims**

Claims 1-24 are all the claims pending in the application. In the Amendment filed November 19, 2010, Applicant amended claims 1, 21 and 22. By this Supplemental Amendment, Applicant is adding new claims 23 and 24 to further recite the invention. These claims are supported by the originally filed disclosure (*see*, page 7 and FIG. 1, for example). No new matter is added.

### **III. Art Rejections**

1. Claims 1-4, 7-9, 11, 13 and 20-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius et al. (US 6,637,431 (Ekelius)) in view of Razeti (US 2003/0108714).
2. Claim 1 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius in view of Razeti and further in view of Fuller et al. (US 2002/0008046 (Fuller)).
3. Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius in view of Razeti and further in view of Lippert (US 4,938,414).

Applicant respectfully traverses the rejections because one of ordinary skill in the art would not have modified the device of Ekelius with the features of Razeti.

Specifically, the proposed modification of the Ekelius blister pack with the peel layer disclosed in Razeti would render the Ekelius device unsatisfactory for its intended purpose. For example, if the foil cover is peeled back from the blisters in Ekelius, then the pharmaceutical contents may undesirably fall out of the blisters before the user puts the suction tube in the blister to inhale the contents. That is, Ekelius is intended to improve the suction operation, wherein a piercing suction tube is accurately placed on the blister to *penetrate the blister seal* with the cutting mechanism (22) that is provided at the bottom of the suction tube 4. Upon penetration, the seal breaks open and the suction tube, which remains in place in the blister, allows the user to inhale the contents through the suction tube without losing a portion of the intended dose. Peeling away the seal before inserting the tube would allow the contents to escape, rendering Ekelius unsatisfactory for this purpose. The pharmaceutical dose would not be maintained in a controlled environment and there would be no manner for ensuring that the entire dose was administered via the suction tube.

“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).” *See* MPEP 2143.01(V).

Also, the proposed modification would change the principle of operation of Ekelius. Ekelius is specifically directed to a system in which a piercing suction tube allows the user to inhale the contents of a blister, and its entire physical design is centered around this operation.

Ekelius provides a case that holds the suction tube and the blister pack. The case assembly is specifically designed to keep the suction tube in place, and the blister pack in position so that a user can easily pierce the blister with the cutting end of the suction tube when a dose needs to be inhaled. While one end has the cutting blade for penetrating the blister, the other end of the suction tube has a mouthpiece for the user to inhale the blister contents. Using a peelable layer, such as that in Razeti, to open the blister and expose the pharmaceutical contents would completely change the principle of operation of Ekelius. The blades at the end of the suction tube would no longer serve to pierce through the seal to allow access to the contents via the suction tube. The assembly would not serve to keep the pharmaceutical dose in a contained manner for administration.

*The proposed modification would completely change the basic principle under which Ekelius operates.*

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). (The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Fuller fails to make up for the deficiencies of the Ekelius/Razeti combination.

For at least the foregoing reasons, the combination of cited references fails to render independent claims 1, 21 and 23 obvious. Moreover, the remaining dependent claims are

patentable for at least the same reasons as the independent claims, by virtue of their dependency therefrom.

#### **IV. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: December 27, 2010